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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,674	03/12/2002	Andreas H. Sarris	016303-007630US	3833
20350	7590	11/19/2003	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,674	SARRIS ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-77 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims included in the prosecution are 1-77.

1. Claims 22-27, 54-59, 69 and 71-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between the chemotherapeutic agent and an anti-tumor agent in claims 22 and 24, 54 and 56 is unclear. The use of trademarks is improper. The examiner suggests ATCC numbers instead.

It is unclear what a mannitol buffer in claim 69. A buffer is a combination of a combination of a weak acid and its corresponding salt (for e.g. Acetic acid-sodium acetate). The vial recited also contains sodium acetate. What does the mannitol buffer contain?

Claims 71-77 provide for the use of liposomal vincristin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 71-77 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-67 and 71-77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-4, 7-12, 15-30 and 71-72 of copending Application No. 09/541,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant 'relapsed cancer' recited in instant claims included lymphoma and leukemia recited in the claims of said copending application and instant 'vinca alkaloid' includes vincristin recited in the claims of said copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6, 8, 13, 21, 28, 31-34, 37, 38, 40, 45, 52, 53, 60-62, 64, 67, 68 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Rahman (4,952,408).

Rahman teaches the treatment of lymphomas and leukemias using vinca alkaloids encapsulated in liposomes. The liposomes contain phosphatidylcholine and cholesterol (note the abstract, columns 1-7, Examples and claims).

6. Claims 1-8, 11-13, 21, 28, 31-34, 37, 38-40, 43-45, 52, 53, 60-62, 64, 67, 68 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Bally (5,595,756).

Bally teaches the treatment of lymphomas and leukemias using vinca alkaloids encapsulated in liposomes. The liposomes contain distearoylphosphatidylcholine and cholesterol. The liposomes are prepared using a pH gradient (note the abstract, columns 1-7, Examples and claims).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-2, 5-13, 28, 60, 62-64, and 68-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Webb (5,741,516).

Webb discloses vinca alkaloid encapsulated in liposomes and the treatment of leukemia. The liposomes contain either cholesterol and sphingomyelin or cholesterol and DSPC. The liposomes are prepared using a pH gradient. The composition is injected intravenously (note the abstract, Figures, Examples and claims).

7. Claims 60-62, 64, 68, 70, 71, 72 and 77 are rejected under 35 U.S.C. 102(a) as being anticipated by Forssen (5,714,163).

Forssen discloses treatment of mice with implanted lymph sarcoma tumor cells by the administration of liposomes containing DSPC and cholesterol and encapsulating vinca alkaloids (note examples).

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-24, 28-56 and 60-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rahman or Bally cited above by themselves or in combination with Benet (5,567,592).

As pointed out above, both Rahman and Bally teach the treatment of leukemias and lymphomas using liposomal vinca alkaloids. Although they do not explicitly teach the treatment of relapsed leukemias and lymphomas, it would have been obvious to one of ordinary skill in the art that the compositions of Rahman, and Bally can be used to treat cancers, which are relapsed with the expectation of obtaining at least similar results. One skilled in the art would be motivated further to use the liposomal compositions of Rahman, and Bally for the treatment of relapsed cancers since Benet teaches that the liposomal therapy reverses the multidrug resistance (MDR) of tumors. One of ordinary skill in heart would be motivated to use a steroid such as prednisone since Benet teaches that steroids reverse MDR (note col. 3, lines 10-25).

10. Claims 1-24, 28-56, 60-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb cited above by themselves or in combination with Benet (5,567,592).

As pointed out above, Webb teaches the treatment of leukemias using liposomal vinca alkaloids. Although they do not explicitly teach the treatment of relapsed leukemias and lymphomas, it would have been obvious to one of ordinary skill in the art that the compositions Webb can be used to treat cancers which have relapsed with the expectation of obtaining at least similar results. One skilled in the art would be motivated further to use the liposomal compositions of Webb for the treatment of relapsed cancers since Benet teaches that the liposomal therapy reverses the multidrug resistance (MDR) of tumors. One of ordinary skill in heart would be motivated to use a

steroid such as prednisone since Benet teaches that steroids reverse MDR (note col. 3, lines 10-25).

11. Claims 1-25 and 27-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rahman or Bally or Webb cited above by themselves or in combination with Benet (5,567,592) as set forth above, in further combination with Hellstrom (5,165,922).

The teachings of Rahman, Bally and Webb have been discussed above.

What are lacking in these references are the explicit teachings of the use of the vinca alkaloids for the treatment of relapsed cancer. Also lacking is a teaching of the administration of the compositions together with monoclonal antibodies. Hellstrom teaches a synergism when chemotherapy is combined with anti-tumor antibodies. According to Hellstrom a breast cancer patient previously responsive to antibody therapy but in relapse achieved complete remission after the combination therapy (note the abstract and columns 2-7. Hellstrom suggests the combination therapy for leukemias and lymphomas (note col. 6, line 17). Hellstrom is further suggestive of the combination chemotherapy of cancers using a combination of anticancer drugs (note Example on col. 6) Hellstrom however, does not teach the use of instant antibodies.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rahman or Bally or Webb cited above by themselves or in combination with Benet (5,567,592) as set forth above, in further combination with Hellstrom (5,165,922) and applicant's statements of prior art.

The teachings of Rahman, Bally, Webb and Hellstrom have been discussed above.

What are lacking in these references are the teachings of the use of instant antibodies.

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According to instant specification, claimed antibodies are known.

The use of art known antibodies or additional anti-cancer agents such as Adriamycin, in combination with the liposomes of Rahman, Bally or Webb would have been obvious to one of ordinary skill in the art because of the synergism suggested by Hellstrom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is 703 308 2440. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703 308 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK